TRANSMITTAL LETTER (General - Patent Pending)	Docket No. 13589

In Re Application Of: **Richard Weisbart, et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/966,119	September 29, 2001	R. B. Schwadron	23389	1644	4420

Title: **METHOD AND COMPOSITION FOR TREATING IMMUNE-MEDIATED DISEASES**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

- **Response to Notification of Non-Compliance Appeal Brief Under 37 C.F.R. 41.37**
- **Appeal Brief**
- **Appendix (VIII-X)**

in the above identified application.

- ☒ No additional fee is required.
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Dated: **February 16, 2005**

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Frank S. DiGiglio

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Richard Weisbart, et al.	**Examiner:**	R. B. Schwadron
Serial No.:	09/966,119	**Art Unit:**	1644
Filed:	September 28, 2001	**Docket:**	13589
For:	METHOD AND COMPOSITION FOR TREATING IMMUNE-MEDIATED DISEASES	**Dated:**	February 16, 2005

Confirmation No.: 4420

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF NON-COMPLIANCE APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Sir:

In response to the Notification of Non-Compliance Appeal Brief (37 CFR 41.37) dated February 1, 2005, Appellants submit a copy of new Appeal Brief in the above-identified appeal.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

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Dated: February 16, 2005

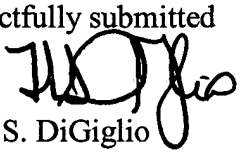
Frank S. DiGiglio

In the new Appeal Brief, Appellants have added Section "IX. Evidence Appendix" and Section "X. Related Proceedings Appendix" in compliance with 37 C.F.R. § 41.37. In addition, Appellants have replaced the heading "Appendix A: Claims involved in the appeal" with the heading "VIII. Claim Appendix" in compliance with 37 C.F.R. § 41.37.

In view of the foregoing amendments, Appellants submit that the new Appeal Brief submitted herewith is in full compliance with 37 C.F.R. § 41.37. Early consideration of the same is respectfully requested.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 19-3886/RCT.

Respectfully submitted



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Confirmation No.: 4420

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APPEAL BRIEF

Sir:

This is an appeal from the Final Action, dated July 29, 2004, in the above-identified patent application. Pursuant to 35 U.S.C. § 134 and 37 C.F.R. § 41.37, entry of this Appeal Brief in support of the Notice of Appeal filed September 29, 2004, in the above-identified application is respectfully requested.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

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Dated: February 16, 2005

Frank S. DiGiglio

I. Real Party in Interest

Research Corporation of Technologies, Inc., a Delaware Corporation, at 101 N. Wilmot Road, Suite 600 of Tucson, Arizona 85711-3365, is the real party of interest in the present appeal.

II. Related Appeals and Interference

There are no other prior and pending appeals, interferences or judicial proceedings known to Appellants that may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in present appeal.

III. Status of Claims

A. Claim Status

Claims 1-7 and 10-27 have been withdrawn pursuant to a Restriction Requirement mailed September 26, 2003.

Claims 8 and 28 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claims 8 and 9 of copending U.S. Application Serial No. 09/672,911 in view of EP 0 064 210 B2; and under 35 U.S. C. §103(a) over European Patent No. 0 064 210 in view of U.S. Patent No. 6,171,549.

Claim 9 has been canceled.

B. Appealed Claims

Claims 8 and 28 are appealed.

IV. Status of Amendments

No amendment has been filed in response to the Final Rejection of July 29, 2004.

V. Summary of Claimed Subject Matter

The invention with respect to independent Claim 8 is directed to a pharmaceutical composition comprising irradiated Cohn Fraction II + III and a pharmaceutically acceptable carrier suitable for oral administration; and set forth in the specification at page 7, line 20 to page 8, line 2; page 9, lines 16-20; page 12, lines 10-15; page 18, lines 9-24 and as shown in Table 1 starting on page 18, for example.

The invention with respect to independent Claim 28 is directed to a composition comprising irradiated Cohn Fraction II + III suitable for oral administration; and set forth in the specification at page 7, line 20 to page 8, line 2; page 9, line 28 to page 10, line 1; page 12, lines 10-15; page 18, lines 9-24 and as shown in Table 1 starting on page 18, for example.

VI. Ground for Rejection to be Reviewed on Appeal

1. Provisional rejection of Claims 8 and 28 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claims 8 and 9 of copending and commonly owned U.S. Application Serial No. 09/672,911 ("the '911 application") in view of EP 0 064 210 B2 to Hardie ("Hardie").

2. Rejection of Claims 8 and 28 under 35 U.S.C. § 103(a) over Hardie and in view of U.S. Patent No. 6,171,549 to Kent ("Kent").

VII. Argument

1. Introduction

The claims on appeal before the Board of Patent Appeals and Interferences ("the Board") are Claims 8 and 28 and are set forth in the annexed Appendix A. The present invention is related to irradiated Cohn Fraction II + III suitable for oral administration.

The subject matter of the present invention is patentably distinct from the separate and collective teachings of the prior art. The prior art references do not teach, disclose or even suggest the present invention. Moreover, there is no suggestion in the prior art to combine the references in the manner that the Examiner has devised, nor is there reasonable expectation of success that this specious combination would achieve the present invention. Notably, in fact, the cited prior art teaches away from the present invention.

2. Provisional Rejection of Claims 8 and 28 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claims 8 and 9 of the '911 application in view of Hardie

As argued below, Appellants respectfully submit that Hardie does not render the present invention obvious. Accordingly, the provisional rejection of Claims 8 and 28 under the judicially created doctrine of obviousness-type double patenting constitutes reversible error. Nevertheless, Appellants are willing to file a terminal disclaimer in the present application in the event that Claims 8-9 of the co-pending '911 application are allowed. Alternatively, in the event that the Board, in view of the present Appeal Brief, passes Claims 8 and 28 of the present application to allowance prior to the allowance of the '911 application, Appellants will cancel Claims 8-9 in the '911 application.

Given that the provisional rejection constitutes reversible error and that it will be overcome in any event, even assuming that the provisional rejection is sustained, reversal of the Examiner's provisional rejection by the Board is respectfully solicited.

3. Rejection of Claims 8 and 28 under 35 U.S.C. § 103(a) over Hardie and in view of Kent

A. The subject matter of Claims 8 and 28 is not rendered obvious by the combined teachings of Hardie and Kent under 35 U.S.C. § 103.

In the Final Action dated July 29, 2004, the Examiner cited EP 0 064 210 B2 to Hardie ("Hardie") and U.S. Patent No. 6,171,549 to Kent ("Kent") in support of the rejection of Claim 8 under 35 U.S.C. § 103. Specifically, the Examiner contends that one skilled in the art would have been motivated to make the claimed products of the present invention because (1) Hardie allegedly teaches a pharmaceutical composition comprising Cohn Fraction II+III (a blood product comprising immunoglobulins) and a pharmaceutically acceptable carrier for oral administration; and (2) because Kent allegedly teaches that blood products, including proteins and antibodies (immunoglobulins), can be sterilized via irradiation. The Examiner has suggested that by employing the sterilization method of Kent to the product of Hardie, one skilled in the art would have expected to achieve the present invention. The Examiner has acknowledged that Hardie does not teach the irradiation of Cohn Fraction II+III. See Final Action, Item 8 starting on page 3.

As argued below, Appellants believe the Examiner's assertion to be erroneous since neither Hardie nor Kent discloses, teaches or suggests a composition or pharmaceutical composition comprising irradiated Cohn Fraction II + III suitable for oral administration as disclosed and claimed in the present invention.

The present invention, for the first time, recognizes that a pharmaceutical composition comprising irradiated Cohn Fraction II+III, when administered to patients having immune-mediated disease, results in a significant clinical improvement in the condition of the patient. The present invention also recognizes that the claimed pharmaceutical composition, when orally administered to patients, exhibits no toxic effects. See the specification, on page 7, line 25 to page 8, line 2.

The primary reference, Hardie, discloses "an oral pharmaceutical composition for human therapeutic use comprising human blood fractionation-derived immune globulin, wherein at least 70% of the immune globulin is IgG." See Hardie, on page 2, lines 1-2 (emphasis added). Hardie also requires that the orally administerable immune serum globulin is hepatitis-safe. See Hardie, on page 3, lines 17-18. Hardie states that the globulin fraction isolated from human blood plasma by Cohn fractionation is merely a starting material for the orally administerable composition. See Hardie, last paragraph on page 4. According to Hardie, the aforementioned starting material includes "Cohn Fraction II+III paste, the hepatitis safety of which is not known, [but] may be rendered so by methods known in the art such as by heat pasteurization in the presence of a stabilizer." *Id.* Hardie further discloses that after such starting material is obtained, it is then suspended in a certain salt solution, at a certain temperature and pH before it is sterile filtered. *Id.* There is no recognition in Hardie that Cohn Fraction II+III can be an orally administerable pharmaceutical composition. While Hardie may teach that a certain composition derived from Cohn Fractionation is orally administerable under conditions of certain salt concentration, temperature and pH, and sterile filtration, there is certainly no recognition in Hardie that Cohn Fraction II+III itself is orally administerable by irradiation. At best, Hardie merely suggests that Cohn Fraction II+III paste can be hepatitis-safe by heat pasteurization in the presence of a stabilizer, which, in fact, teaches away from the present invention.

Appellants maintain that in the absence of the requisite teaching of the present invention, one skilled in the art would not be motivated to make an orally administerable pharmaceutical composition comprising irradiated Cohn Fraction II+III. Even assuming one skilled in the art would have been motivated to try, there would have been no reasonable expectation of achieving the present invention.

A rejection of claimed subject matter as obvious under 35 U.S.C. § 103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed device or composition, or carry out the claimed process; and (2) whether the prior art would have suggested that in so carrying out the claimed process, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). There is no suggestion in the art of record to irradiate Cohn Fraction II+III for oral administration, as disclosed by the present invention. Nor is there any expectation in the prior art on this record that irradiated Cohn Fraction II+III is orally administerable.

Kent explicitly states that products prepared from humans contain unwanted and potentially dangerous contaminants such as viruses, bacteria, yeasts, molds, mycoplasmas and parasites. See Kent, col. 1, lines 15-18. While disclosing a method for sterilizing blood products through low-dose irradiation, Kent does not teach, or even suggest, that the IgG composition disclosed by Hardie, let alone Cohn Fraction II+III itself, can be irradiated and orally administered. In fact, Kent teaches nothing about oral administration of a blood product *per se*. The objective of Kent appears to be to prevent the spread of viral disease through blood transfusion (intravenously) or organ transplant. See Kent, col. 1, lines 20-22 and col. 3, lines 19-23. Accordingly, Kent not only fails to suggest that, as asserted by the Examiner (see Final Action, last paragraph of Item 8), Cohn Fraction II+III itself can be orally administerable once irradiated but also actually implies that the irradiation method is employed for sterilizing blood products for organ transplant or intravenous administration. Appellants respectfully submit that it is well known in the art that a blood product for intravenous administration is not necessarily administerable via oral or other routes. In fact, it is well accepted in the art that a blood product

should only be administered intravenously if other routes of administration have not been evaluated. Thus, it is evident that even assuming that an irradiated Cohn Fraction II+III could be intravenously administerable for a blood transfusion, such teaching alone does not suggest that the irradiated Cohn Fraction II+III can be orally administered.

Kent fails to teach irradiation of Cohn Fraction II+III. Kent also fails to suggest an oral product. Considering that Hardie is essentially NOT the product of the present claims in the first instance, the combination of references identified by the Examiner does not remotely lead to the claimed invention.

Where patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. *In re Lee*, 277 F.3d 1338, 1343, 61 U.S.P.Q.2d (BNA) 1430, 1433 (emphasis added). In the present case, there is clearly no teaching, motivation or suggestion to combine Hardie with Kent.

One skilled in the art would not have been motivated to combine a method for irradiating an intravenously administered blood product with a composition for oral administration. In other words, Hardie and Kent, if combined, at best, teach that an oral composition comprising 70% or more IgG, which is derived from a blood product, can be sterilized via irradiation without adverse effect to the structural integrity of the IgG molecule. However, one may not extrapolate sterilized IgG to irradiated Cohn II+III suitable for oral administration. The IgG composition of Hardie and the claimed Cohn Fraction II+III are two different blood products; and Kent suggests only the sterilization of products for intravenous use. Based on the teachings of Hardie and Kent alone, it is not obvious to one skilled in the art that

low dose irradiation would have rendered Cohn Fraction II+III orally administerable for the effective treatment of immune related disease or anything. Thus, Kent does not ameliorate the deficiencies of Hardie. Moreover, the teachings of Kent fail to provide any motivation to combine the references.

In the Final Rejection, the Examiner has improperly presumed that the pharmaceutical composition of Hardie comprises Cohn Fraction II+III and has implied that an intravenously administered blood product is orally administerable. Such presumptions are either formed with the distinct benefit of hindsight based on the teaching of the present invention, or based on the Examiner's own belief or some other unknown authority. In fact, as discussed above, an intravenously administered blood product is not an orally administered product. Moreover, Hardie merely discloses that a product derived from Cohn Fraction II+III, not the Fraction itself, is orally administerable. In considering obviousness in patent applications, the factual question of motivation is material to patentability, and cannot be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to a combination of references, simply to use that which the inventor taught against its teacher. *In re Lee*, 277 F.3d at 1343, 61 U.S.P.Q.2d (BNA) at 1434.

Even assuming, *arguendo*, that one skilled in the art was motivated to combine the teachings of Hardie and Kent at the time the present application was filed, there would have been no reasonable expectation of success to achieve the present invention. One skilled in the art would not have reasonably expected that Cohn Fraction II+III, when irradiated, was orally administerable. Unlike the IgG composition in Hardie, Cohn Fraction II+III of the present invention is not required to be sterile filtered. Further, nowhere does Kent teach or suggest that irradiated blood products can be orally administered. The Examiner has offered no record to

suggest, nor does the art acknowledge, that an intravenously administerable blood product will necessarily be orally administerable.

Thus, based on the teachings of the prior art of record, one skilled in the art at the time the present application was filed would not have had a reasonable expectation of success of obtaining an orally administerable Cohn Fraction II+III, employing irradiation.

Based on Kent and Hardie, *arguendo*, it was merely a possibility that irradiated Cohn Fraction II+III might be orally administerable. However, such possibility appears based on nothing more than mere speculation or wishful thinking. Appellants submit that the sheer speculation based on the teaching of Hardie and Kent fails to meet the standard of obviousness under 35 U.S.C. § 103. *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988). At most, such speculation provides nothing more than an invitation to experiment; however, it is axiomatic that an invitation to try is not the standard under 35 U.S.C. § 103. *In re O'Farrell*, 253 F.2d 894, 903, 7 U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988). "As stated in *In re Eli Lilly and Co.*, . . .[a]n 'obvious-to-try' situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued." *Ex parte Goldgaber*, 41 USPQ 2d 1172, 1177 (B.P.A.I. 1996) (quoting *In re Eli Lilly and Co.*, 902 F.2d 943, 945, 14 USPQ 2d 1741, 1743 (Fed. Cir. 1990)).

Furthermore, there had been a long-felt need for an effective composition for the treatment of immune-mediated diseases at the time the present invention was filed. See the specification, page 7, lines 12-15. By identifying an oral pharmaceutical composition comprising irradiated Cohn Fraction II+III, the present invention for the first time provides a

successful solution to this long-standing problem. The hypothetical combination of the cited references does not defeat an invention where the evidence shows that long-standing problems have been solved. *Kalman v. Kimberly-Cark Corp.*, 713 F.2d 760, 774, 218 U.S.P.Q. 781, 791 (Fed. Cir. 1995). The consistent criterion for the determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Long-felt need in the face of prior art later asserted to lead to a solution tends to negate the proposition that the combination of such prior art would have been obvious. *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1547, 41 U.S.P.Q.2d, 1238, 1245 (Fed. Cir. 1997) (emphasis added). Thus, by solving a long-standing problem, the present invention is not obvious in view of Hardie and Kent.

B. The Examiner has improperly used hindsight arguments to reject the claims under 35 U.S.C. § 103.

As discussed above, it is only with the benefit of the present application that the Examiner establishes a nexus between the claimed invention and the cited prior art teaching. However, "[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corporation v. Lydall, Inc.*, 159 F.3d 534, 546, 48 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 1998).

Appellants respectfully submit that the Examiner has utilized the considerable benefit of hindsight in suggesting that it would have been obvious to employ an irradiation

method for sterilization, as described by Kent, to sterilize the immunoglobulin composition described by Hardie, to successfully achieve the present invention. The Court of Appeals for the Federal Circuit in *In re Bond*, 910 F.2d 831, 834, 15 U.S.P.Q.2d 1566, 1568 (Fed. Cir. 1990) held that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching, suggestion or incentive supporting the combination." See also, *Texas Instruments Inc. v. U.S. Int'l Trade Commission*, 988 F.2d 1165, 26 U.S.P.Q.2d 1018 (Fed. Cir. 1993).

The claimed invention embodies oral compositions comprising irradiated Cohn Fraction II+III. The Examiner offered no reference that suggests that irradiated Cohn II+III is suitable for oral administration. Hardie, which is directed to an oral pharmaceutical composition comprising IgG derived from a blood product, does not suggest Cohn Fraction II+III let alone irradiated Cohn II+III. Thus, the primary reference cited by the Examiner fails to teach or even remotely suggest an essential embodiment of the claimed invention.

Furthermore, while disclosing a method of sterilizing blood products by irradiation, the secondary reference, Kent, does not teach that irradiated blood products are orally administered. Nor does Kent disclose irradiated Cohn Fraction II+III. Specifically, Kent merely shows low dose irradiated blood products are safe for blood transfusion or organ transplant. Thus, the Examiner has offered no reference on this record which suggests irradiated Cohn Fraction II+III suitable for oral administration, as disclosed and claimed by the present invention.

It is well settled that in determining obviousness, the inquiry is not whether each element of the invention existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed. *Hartness International, Inc. v. Simplimatic Engineering Company*, 819 F.2d 1100, 2 U.S.P.Q.2d 1826 (Fed. Cir. 1987). One

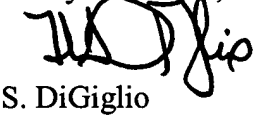
skilled in the art would not look to the teachings of Hardie and Kent in order to achieve the present invention, whether in combination, or otherwise; and the Examiner has provided no convincing reason, no less a *prima facie* basis why such combination would be obvious to the skilled artisan. None of the cited references provide any incentive or encouragement to combine the references as recommended by the Examiner; nor does this specific combination result in the claimed invention. Accordingly, it is improper for the Examiner to combine the cited references, where the references do not suggest such a combination, in order to reject Appellants invention under 35 U.S.C. § 103. *ACS Hospital Systems, Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984).

Accordingly, Claims 8 and 28 are not rendered obvious by the teachings of Hardie and Kent pursuant to 35 U.S.C. §103(a).

4. Conclusion

For all the foregoing reasons, it is believed that the Examiner's final rejection of Claims 8 and 28 under 35 U.S.C. §103 and provisional rejection of Claims 8 and 28 under the judicially created doctrine of obviousness-type double patenting constitute reversible error.[1] It is, therefore, respectfully requested that the Board reverse the Examiner's rejections and pass Claims 8 and 28 on appeal to allowance.

Respectfully submitted,



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[1] Appellants also submit that, even assuming the absence of reversible error, the rejection under the judicially created doctrine of obviousness-type double patenting can be overcome by filing a terminal disclaimer or cancelling the corresponding claims in the co-pending application as discussed above.

VIII. Claims Appendix

8. (Previously presented) A pharmaceutical composition comprising irradiated Cohn Fraction II + III and a pharmaceutically acceptable carrier suitable for oral administration.

28. (Previously presented) A composition comprising irradiated Cohn Fraction II + III suitable for oral administration.

IX. Evidence Appendix

N/A. There has been no evidence submitted pursuant to 37 CFR § 1.130, 1.131 or 1.132.

X. Related Proceedings Appendix

N/A. There are no other prior and pending appeals, interferences or judicial proceedings known to Appellants that may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in present appeal.